



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,056	09/20/2001	Mark L. Tykocinski	285332-00002-2	6690

28289 7590 06/28/2005

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
----------	--------------

1643

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/957,056	Applicant(s) TYKOCINSKI ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 51, 52, 55, 56 and 59-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 51, 52, 55, 56 and 59-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 18, 2005 has been entered.

2. Claims 23, 51, 52, 55, 56 and 59-61 are pending.

Claims 23, 55 and 56 have been amended.

Claims 53 and 54 have been cancelled.

Claims 23, 51, 52, 55, 56 and 59-61 are examined on the merits.

Maintained Grounds of Objection

Specification

3. The disclosure continues to be objected to because of the following informality:
on page 13, line 14 it is not clear what the recitation [???] means.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

4. The rejection of claims 23, 51, 52 and 55-61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to claim 23. Claims 53 and 54 have been cancelled.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 23, 51, 52, 55, 56 and 59-61 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Claims 53 and 54 have been cancelled.

Applicants have amended claim 23 in the submission filed April 18, 2005.

Applicants assert the claims recite specific lipidated proteins and specific categories and fusion proteins and consequently the claims meet all requirements of 112 and are allowable, see Remarks, page 4, paragraph 5. Applicants aver the Examiner has not pointed to one piece of actual evidence that provides basis for the assertion that the Applicants are not compliant with the requirements of written description and "...the invention is clearly explained in the specification", see bridging paragraph of pages 4 and 5 and page 5, paragraph 2. Applicants reference the declaration by Dr. Mark

Art Unit: 1642

Greene which Applicants state "...addresses the issue of why the claimed subject matter was in Applicants' possession at the time the application [was filed].", see page 6, paragraph 2. Applicants conclude arguments noting it seems the Examiner has made conclusory statements, doesn't address the Greene declaration and attach *In re Alton*, 76 F. 3d 1168, 37 USPQ 2D 1578 (Fed. Cir. 1996) in support of their arguments, see page 6, paragraph 3. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' arguments are not commensurate in scope with the claims.

Applicants note the invention is clearly explained in the specification and "one skilled in the art would recognize the necessity for selecting the proper combinations of proteins to carry out the invention" and "[a]dditional guidance on selection of the proper proteins is also provided in the specification.", see page 5, paragraphs 2 and 3. This information is not in the claims. Information regarding the selection of "the proper combinations of proteins" is not in the claims. Applicants are reminded that the claims are given the broadest and reasonable interpretation. The genus claimed by Applicants is not limited to cells having proteins that function and do not function. While Applicants have amended the claims to include a fusion protein having costimulatory, inhibitory or adhesion function these broad limitations continue to read on a number of proteins and this information does not impart knowledge to one skilled in the art regarding the structure of the proteins. Asserted function does not translate into a clear showing of possession. Evidence is not required for this type of rejection when the breadth of the claims read on a genus of molecules with a plurality of features that are broadly

Art Unit: 1642

described. The Examiner has not made conclusory statements, but reasoned statements that plainly address and set forth why Applicants' are not in possession of a multitude of cells comprising numerous proteins and protein derivatives, which are supposed to carry out several functions as set forth by the claim language. It is of record that while Applicants may be entitled to preferred embodiments the claims do not address those nor would those species be representative of the claimed genus. The claims as written continue to embrace enumerable species not adequately described. There is substantial variation with the genus and the claims as written do not present a representative showing of species within the claimed genus. As Applicants' claims are written the cell could include countless numbers of proteins.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Conclusion

6. Claims 23, 51, 52, 55, 56 and 59-61 are free of the art.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER


Alana M. Harris, Ph.D.

27 June 2005